REMARKS

This Reply and the Amendments above are in response to an Office Action mailed March 30, 2009.

Status of the Claims

Claims 1 and 46-54 were previously presented to the Examiner.

Claims 1 and 46-54 are presented now with claims 31, 33 and 35 currently amended.

In the Office Action the Examiner incorrectly spelled the name of the elected compound. The compound, as found in the specification, is correctly spelled as follows: -- 4-[2-(6-methyl-pyridin-2-yl)-pyrazolo[1,5-a]pyridin-3-yl]-pyrimidin-2-ylamine -- This compound was elected in the Reply dated 10-1-07, and the name was repeated in the Office Action mailed 11-20-07. In the last Office Action the Examiner appears to have characterized the elected compound as having moieties found on example 14 of Gudmundsson. The Examiner made the following comment, "Thus, the examiner will extend the search to other non-elected species represented by the formula I (where X1, X2, X3, X4 is CRx, Y1 and Y 2 is N; R1 is halo (i.e., fluoro); R2 is alkylsulfanyl (i.e. methylsulfanyl); m=1; n=1; methylsulfanyl); Rx is hydrogen) and examine for prosecution on the merits of the case." While Applicant agrees that in the elected species X1, X2, X3, X4, is CRx, and both Y1 and Y 2 is N; the Examiner is mistaken if the conclusion is that R1 is halo (i.e., fluoro); R2 is alkylsulfanyl. This is not true of the elected species. Gudmundsson, discussed below, does not disclose any of the compounds of this invention.

In the elected species R^1 is CH_3 and R^2 is NH_2. It is unclear why the Examiner came to the conclusion that "Claims 1, 30, 32, 34, 46, 47, 48, 49, 50, 51 and 53 read on the elected species. Claims 36-45, 52 and 54 are withdrawn from further consideration by examiner as being drawn to non-elected invention." (emphasis added) The elected species, in fact, is within the scope of all of these claims. The elected species is within the scope of claims 52 and 54 because they both allow both R^2 to be "NH_2," and R^1 to be CH_3. In addition, there was never a restriction requirement imposed such that the scope of the claims examined should be narrowed to any particular variables. In the original restriction requirement mailed 7/31/2007, the application was restricted by

method of treatment, it was never restricted by molecular moiety. The election of a species was made in order to start the examination, but when an elected compound is found free of the art the examination must then be expanded until a compound is found that reads on the art.

See MPEP section 806.04 and reference to 37 CRF 1.146, Election of species, and related sections. "In the first action on an application containing a generic claim to a generic invention (genus) and claims to more than one patentably distinct species embraced thereby, the examiner may require the applicant in the reply to that action to elect a species of his or her invention to which his or her claim will be restricted if no claim to the genus is found to be allowable. " MPEP section 806.04 and reference to 37 CRF 1.146. Thus, the rules require that each generic claim be fully considered after election of a species, from smaller to larger formula, until all claims are allowed or until it is determined that a genus claim is not allowable.

Applicant agrees that claims 36-45 are withdrawn until rejoined, but claims 52 and 54 should both be examined with the other claims. The elected compound, as stated above is,

-- 4-[2-(6-methyl-pyridin-2-yl)-pyrazolo[1,5-a]pyridin-3-yl]-pyrimidin-2-ylamine --

This compound has a R^2 that is NH_2 and it has a R^1 that is CH_3. Both of these moieties are allowed by both claims 52 and 54 and thus these claims should be examined. In fact claim 54 has the elected species as one of its named compounds. It is one of only 8 compounds. The elected compound is the second listed compound. None of the 8 species of claim 54 have been identified as being restricted out of the pending claims, nor are they disclosed by the art. In claim 52, "n is 1 and each R^2 is independently guanadino, amidino, $-NH_2$, ..." Thus, the elected species is within the scope of the claim. Applicant respectfully requests reconsideration of the conclusion that claims 52 and 54 be withdrawn from further consideration. These claims should be evaluated on their merits.

The Examiner further stated that "Claims 31, 33 and 35 are objected as being improperly depending on cancelled claim 29." The Examiner stated that claim 35 has "not been further treated on the merits." Applicant has amended claims 31, 33 and 35 to

properly claim dependency. After entry of these amendments, claims 31, 33 and 35 should also be examined.

Claim Rejection – 35 USC § 102

The Examiner stated that "Claims 1, 30, 32, 34, 46, 47, 48, 49, 50, 51 and 53 are rejected under 35 U.S.C. § 102(e) as being anticipated by Gudmundsson, et al. (US 7199120B2) here, "Gudmundsson."

The Examiner described certain features of Gudmundsson, such as, "Gudmundsson discloses pyrazolo-pryidine derivatives represented by the formula (I) including Example 14 that is useful for the prophylaxis or treatment of viral infections, wherein said compound is prepared in various dosage forms and administered to humans in the range of 0.02-5000mg per day, preferably 100-1500 mg per day (abstract; column 18, line 56 through column 22, line 58)."

"The prior art directing administration of same compound in overlapping dosage amount (see page 27, lines 11-17 of the instant specification) inherently possessing therapeutic effect for the same ultimate purpose as disclosed by applicant anticipates the claimed invention even absent explicit recitation of underlying mechanism."

"To the extent that the claims 1, 30, 32, 34, 46, 47, 48, 49, 50 51 and 53 allows for the inclusion of any patient population, as long as the same compound is administered to body of the patient in overlapping dosage amounts." End of Examiner quote.

Applicant traverses the rejection because Gudmundsson does not disclose the compounds claimed by the application.

The Gudmundsson compounds are shown below, both generic formula and the specific formula for Example 14 are provided at the top of the next page.

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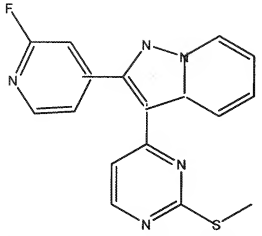
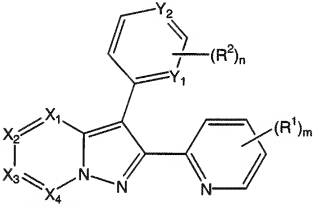


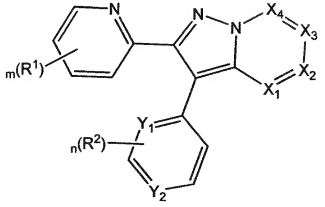
Example 14 from Gudmundsson, above.



(I)

Applicant's Formula I, above.

(I)



Applicant's Formula I, above, (rotated 180 degrees.).

The structures on the previous page clearly show the differences between the Gudmundsson compounds, in particular Example 14 and applicant's compounds. In both documents the core nucleus has a pyrazolo (or -(pyrazolo(pyridine)) attached with a single bond to a pyridine; however, all the Gudmundsson examples, save one, have the pyridine attached to the pyrazolo with the bond at the 4 position of the pyridine, (named in Gudmundsson as ... -4-pyridinyl]pyrazolo-....). Compare the Gudmundsson compounds with Applicant's compounds. Applicant's compounds have the pyrazolo attached at the 2 position of the pyridine, (named ... - pyridin-2-yl)pyrazolo-...). See Applicant's Formula, above. See all of the named compounds in claim 54. Gudmundsson has one example of a 3-pyridinyl(pyrazolo), see Example 3, but there are no examples of a pyridinyl-pyrazolo with a 2 position pyridine attached to the pyrazolo.

Anticipation under 35 USC § 102 for a chemical compound requires disclosure of the same specific compound that is claimed. See *Ex parte Westphal,* 223 USPQ 630 (Bd. Pat. App. 1983) where the Board reversed an examiner's assertion of a § 102 anticipation where the reference, Fawzi, disclosed a compound substituted at a particular position with alkyl having 1 to 8 carbon atoms, but did not specifically name the claimed tert-butyl radical. The Board found the Fawzi patent did not provide the precision necessary for anticipation under § 102. *Ex parte Westphal,* 223 USPQ at 631. See also, *In re Arkley,* 455 F.2d 585, 587, 172 USPQ. 524, 526 (CCPA 1972), where the reference must direct one to the compound itself without the need for any picking and choosing and combining various disclosures.

The law is clear that anticipation requires disclosure of the exact compound being claimed. Here it is clear that the Gudmundsson compounds do not anticipate Applicant's compounds.

Furthermore the Gudmundsson compounds are not designed to modulate the signaling pathway components of the TGFβ family to prevent/treat disorders related to the malfunctioning pathway, instead they are is described as being useful to treat genital herpes and other viral infectious diseases.

The argument that the inherent administration of the Gudmundsson compounds would inherently inhibit the TGFβ signaling pathway fails for two reasons. There is no evidence the Gudmundsson compounds were actually administered to patients and even

if they were, because they are different compounds there would be no inherent administration of the same compounds described by the Applicant.

Conclusion

For all of the reasons above, Applicant believes all the pending claims should be allowed. Applicant invites the Examiner to discuss the application with Applicant's representative, contact information below, should any claim be found not allowable.

EXTENSION OF TIME UNDER 37 CFR § 1.17 SHOULD NOT BE REQUIRED

This is a response to an Office Action mailed on March 30, 2009. It is believed that no extension of time under 37 C.F.R. § 1.17 is required, if for any reason charges are required to prevent abandonment of the application, Applicant requests such fees be taken from Deposit Account No 503145, referencing attorney docket number 223255/A165US/121026, and advise me of the charge immediately.

Respectfully submitted,

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